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EXAMINER
COLBERT, ELLA

ART UNIT	PAPER NUMBER
3624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/650,482	Applicant(s) STEEN ET AL.
	Examiner Ella Colbert	Art Unit 3624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *28-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-40 are pending in this communication filed 03/12/01 entered as Preliminary Amendment A.

2. The IDS submitted 03/01/01 has been considered and entered as paper no. 5.

3. The Address Change Correction filed 08/02/02 has been entered as paper no. 6.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to data processing and database and file management, classified in class 707, subclass 104.1.

II. Claims 16-27, drawn to remote ordering of medication, classified in class 705, subclass 26.

III. Claims 28-40, drawn to dispensing medication, classified in class 700, subclass 231.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I, claims 1-15, drawn to data processing and file management, classified in class 707, subclass 104.1, and Group II, claims 16-27, drawn to remote ordering of medication, classified in class 705, subclass 26 and Group III, drawn to dispensing medication, classified in class 700, subclass 231 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that Group I and Group II the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and Group III that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the

instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the patentability of the steps of creating a record, retrieving information, and generating a medication specific label in Group III are not required for Group I and Group II. The pharmacy network, pharmacy server, and pharmacy client in Group I can be used for accepting and processing orders. The order maintenance unit, the formulary unit, and customer unit can be used for creating the order and presenting the information. The subcombination in Group III has separate utility such as creating the record for the order, retrieving the information, and generating a medication label that can be used for the dispensing of medication. Thus, Group I, Group II, and Group III have separate utilities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I and Group II is not required for Group III, restriction for examination purposes as indicated is proper.

5. An election to the Restriction requirement was made in a telephone conference on August 11, 2003 with Applicants' Representative, Mr. Patrick Y. Ikehara. The election was made without traverse and the elected invention was Group I and a faxed amendment was made to incorporate Group II. Claims 1-27 will be examined. Group III, claims 28-40 have been canceled without prejudice as to filing a divisional application as to the non-elected claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,845,255) Mayaud in view of (US 5,924,074) Evans and further in view of Official Notice.

With respect to claim 1, Mayaud teaches, A pharmaceutical administrative system comprising: a pharmacy network including a pharmacy server and at least one pharmacy client system, the at least one pharmacy client system configured to accept and process orders for medications (col. 7, lines 13-35); and a service center network including a service center server and a service center client system, the service center network coupled to the pharmacy network and configured with a global database including a plurality of formulary records (col. 7, lines 35-45 and col. 11, lines 1-17). Mayaud did not teach, wherein the service center server supplies the pharmacy server at least one of the plurality of formulary records upon request by a pharmacy client system when a order is processed.

Evans discloses, wherein the service center server supplies the pharmacy server at least one of the plurality of formulary records upon request by a pharmacy client system when a order is processed (col. 11, lines 65-67, col. 12, lines 1-15 and lines 56-67, col. 13, lines 1-30, and fig. 24 (406, 408, 410, 414, 416, 418, 430, 432, &

434). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a service center server that supplies the pharmacy server with at least one of the plurality of formulary records upon request by a pharmacy client system when a order is processed and to modify in Mayaud because such a modification would allow Mayaud to allow a healthcare provider to have easy access to the medication records of the patient.

With respect to claim 2, Mayaud teaches, the pharmaceutical administrative system of claim 1 wherein the global database further includes a plurality of order records, each order record including order information for an order accepted and processed by the at least one pharmacy client system (col. 20, lines 32-40).

With respect to claim 3, Mayaud teaches, the pharmaceutical administrative system of claim 1 wherein the global database further includes a plurality of customer records, each customer record including contact and formulary information for at least one customer (col. 16, lines 18-49).

With respect to claim 4, Mayaud teaches, the pharmaceutical administrative system of claim 2 wherein the global database further includes a plurality of patient records, each patient record including contact information and medication history for at least one patient (col. 17, lines 44-43, col. 19, lines 47-62, and col. 20, lines 5-12).

With respect to claim 5, Mayaud teaches, the pharmaceutical administrative system of claim 3 wherein the pharmacy client system is further configured to generate medication specific label containing medication identification information (col. 28, lines 50-67, col. 29, lines 1-65, and fig. 15 (182, 184, 186, & 188).

With respect to claim 6, Mayaud teaches, the pharmaceutical administrative system of claim 5 wherein the pharmacy client system is configured to provide updates to the patient, customer, and formulary records in the global database (col. 31, lines 50-67 and col. 32, lines 1-36).

With respect to claim 7, Mayaud teaches, the pharmaceutical administrative system of claim 6 wherein updates to the formulary records include modification to the ingredients of the medication (col. 36, lines 1-9, col. 35, lines 44-67, and fig. 11 (128 & 130).

With respect to claim 8, Mayaud and Evans did not teach, the pharmaceutical administrative system of claim 7 wherein updates to the modification to the ingredients of the medication include changes to amounts of caloric content in the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the modifications to the ingredients of the medication include modifications to electrolytes in the medication because such a modification in Mayaud and Evans would allow Mayaud and Evans to have substances that dissociate into two or more ions, to some extent, in water.

With respect to claim 9, this dependent claim is rejected for the similar rationale given above for claim 8.

With respect to claim 10, Mayaud teaches, the pharmaceutical administrative system of claim 7 wherein the pharmacy client system is configured to verify the updates to the formulary records in the global database (col. 6, lines 59-67 and col. 7, lines 1-2 and lines 30-45).

With respect to claim 11, Mayaud and Evans did not teach, the pharmaceutical administrative system of claim 7 wherein the medication specific label is for an intravenous solution and the medication identification information includes a refractive index associated with the intravenous solution. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a refractive index of the intravenous solution and to modify in Mayaud and Evans because such a modification would allow Mayaud and Evans to have the information regarding the refractive index since the refractive index increases with the atomic number of constituent atoms in the in the intravenous solution.

With respect to claim 12, Mayaud and Evans did not teach, the pharmaceutical administrative system of claim 7 wherein the medication specific label is for an intravenous solution and the medication identification information includes a level of potassium associated with the intravenous solution. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific label for an intravenous solution and the medication identification information to include a level of potassium associated with the intravenous solution and to modify in Mayaud and Evans because such a modification would allow Mayaud and Evans to use an intravenous solution for medical conditions such as dehydration to put the electrolytes back into a person's body.

With respect to claim 13, Mayaud and Evans did not teach, the pharmaceutical administrative system of claim 7 wherein the pharmacy client system is configured to

generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pharmaceutical system wherein the pharmacy client system is configured to generate a calcium phosphate solubility curve for ~~the~~ an order accepted and processed by the at least one pharmacy client and to modify in Mayaud and Evans because such a modification would provide a time release of the compounds of calcium salts of phosphoric acid which are frequently used as calcium supplements.

With respect to claim 14, Mayaud teaches, the pharmaceutical administrative system of claim 6 further comprising a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time (col. 17, lines 44-52, col. 46, lines 16-31, and fig. 16).

With respect to claim 15, Mayaud teaches, the pharmaceutical administrative system of claim 6 wherein the pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network (col. 1, lines 46-67, col. 2, lines 1-11, and col. 6, lines 59-64).

8. Claims 16-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,758,095) Albaum et al, hereafter Albaum in view of (US 5,737,539) Edelson et al, hereafter Edelson and further in view of Official Notice.

With respect to claim 16, Albaum teaches, the pharmaceutical administrative system of claim 1 wherein the pharmacy client system comprises: an order maintenance unit configured to create an order for medication for at least one customer and at least one patient (col. 3, lines 3-20); a formulary unit coupled to the order maintenance and presenting information about the medication to the order maintenance unit (col. 3, lines 21-47); a customer unit coupled to the order maintenance unit and presenting information relating to contact and purchasing information for the at least one customer ordering the medication (col. 7, lines 7-24); and a patient unit coupled to the order maintenance unit and the customer unit and presenting information relating to contact and medical information for the at least one patient (col. 10, lines 18-43). Albaum did not teach, wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication. Edelson discloses, wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication (col. 12, lines 42-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication and to modify in Albaum

because such a modification would allow Albaum to have a system that is effectively cognizant of the ongoing prescribing activity.

Albaum discloses, the pharmaceutical administrative system of claim 1 wherein the pharmacy client system comprises: an order maintenance unit configured to create an order for medication for at least one customer and at least one patient (col. 3, lines 3-30); a formulary unit coupled to the order maintenance and presenting information about the medication to the order maintenance unit (col. 3, lines 21-47); a customer unit coupled to the order maintenance unit and presenting information relating to contact and purchasing information for the at least one customer ordering the medication (col. 7, lines 7-24 and col. 10, lines 18-32); and a patient unit coupled to the order maintenance unit and the customer unit and presenting information relating to contact and medical information for the at least one patient (col. 10, lines 33-43); wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication (col. 10, lines 44-67).

With respect to claim 17, Albaum teaches, the pharmacy client system of claim 16 wherein the medication is an intravenous solution (col. 11, lines 60-67 and col. 12, lines 1-3).

With respect to claim 18, Albaum and Edelson did not teach, the pharmacy client system of claim 17 wherein the order maintenance unit is configured to validate the modifications to the ingredients by generating a calcium phosphate solubility curve for the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the order

maintenance unit configured to validate the modifications to the ingredients by generating a calcium phosphate solubility curve for the medication and to modify in Albaum and Edelson because such a modification would provide a time release of the compounds of calcium salts of phosphoric acid which are frequently used as calcium supplements.

With respect to claim 19, this dependent claim is rejected for the similar rationale given above for claim 18.

With respect to claim 20, this dependent claim is rejected for the similar rationale given above for claims 18 and 19.

With respect to claim 21, Albaum and Edelson did not teach, the pharmacy client system of claim 20 wherein the order maintenance unit is configured to generate medication specific labels for the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the order maintenance unit configured to generate medication specific labels for the medication and to modify in Albaum and Edelson because such a modification would allow Albaum and Edelson to have a prescription delivery system to generate the invoice and label and other documentation prior to delivering the medication to the patient.

With respect to claim 22, Albaum and Edelson did not teach, the pharmacy client system of claim 21 wherein the medication specific labels for the medication includes information about a refractive index of the intravenous solution. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the

invention was made to have the medication specific labels for the medication include information about a refractive index of the intravenous solution and to modify in Albaum and Edelson because such a modification would allow Albaum and Edelson to have the information regarding the refractive index since the refractive index increases with the atomic number of constituent atoms in the in the intravenous solution.

With respect to claim 23, Albaum and Edelson did not teach, the pharmacy client system of claim 22 wherein the medication specific labels for the medication includes information about a level of potassium in the intravenous solution calculated using flame photometry. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a level of potassium in the intravenous solution calculated using flame photometry and to modify in Albaum and Edelson because such a modification would allow Albaum and Edelson to have a major intracellular cation that is widely distributed in the body in muscle tissue, nerve tissue, blood cells, and plasma which is filtered in the glomerulus, absorbed in the proximal tubule and finally excreted by exchange for sodium in the distal tubule. The reliability depends on the proper maintenance of the flame photometer and the salient features. If low serum potassium values are observed due to low intake of dietary potassium over a period of time or increased loss through kidney, vomiting or diarrhea and increased secretion of adrenal steroids or some diuretics that promote the loss of potassium a flame photometer (digital flame photometer) for simultaneous measurement is useful in these medical conditions.

With respect to claim 24, Albaum teaches, the pharmacy client system of claim 23 wherein the modifications to the ingredients of the medication includes modifications to caloric content of the medication (col. 10, lines 17-43).

With respect to claim 25, this dependent claim is rejected for the similar rationale given above for claim 24.

With respect to claim 26, Albaum and Edelson did not teach, the pharmacy client system of claim 23 wherein the modifications to the ingredients of the medication includes modifications to electrolytes in the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the modifications to the ingredients of the medication include modifications to electrolytes in the medication because such a modification in Albaum and Edelson would allow Albaum and Edelson to have substances that dissociate into two or more ions, to some extent, in water.

With respect to claim 27, this dependent claim is rejected for the similar rationale as given above for claim 26.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

On-line Medical Dictionary; disclosed medical terms and definitions.

Murakami (US 6,181,979) disclosed a medication processing system.

Boyer et al (US 5,907,493) disclosed a pharmacy dispensing system.

Reichert (US 5,970,462) disclosed an on-line pharmacy refill system.

McGauley et al (US 5,899,998) disclosed a medical records updating system.

Williams et al (US 5,597,995) disclosed an automated medical prescription fulfillment system.

Halvorson (US 4,847,764) disclosed dispensing drugs.

Inquiries

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ella Colbert whose telephone number is 703-308-7064. The examiner can normally be reached on Monday-Thursday from 6:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin can be reached on 703-308-1038. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

E. Colbert
August 23, 2003